

Restriction is only proper if the identified groups are independent or patentably distinct. The burden is on the Office to provide reasons and/or examples to support its conclusion that the identified groups are independent or distinct (MPEP § 803). For discussion purposes, the Groups as they are discussed below have retained the numbering as provided in the Office Action of December 18, 2001; each of those Groups contain five separately restricted subgroups.

The Office has characterized the relationship between Groups 1-6, 10-14, 23-26, 51-53, and 68 as being drawn to separate and distinct products which are made by materially different methods and are used in materially different methods which have different modes of operation, different functions and different effects. No section of the MPEP has been cited for the standard for determining patentable distinctness between these groups. The Office has not provided an explanation or an example to support the determination that methods used to make the products are materially different; nor is support given for the assertion that the products are used in materially different methods. The Office has simply stated a conclusion of material distinctness, without support.

The Office has characterized the relationship between Groups 7-9, 15-22, 27-50, and 54-67 as being drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. No section of the MPEP has been cited for the standard for determining patentable distinctness between these groups. The Office has not provided an explanation or an example to support the determination that the methods are materially different. The Office has simply stated a conclusion of material distinctness, without support.

The Office asserts that the relationships between:

- (a) Groups 4-6 and the methods of Groups 7-9
  - (b) Group 2 and the methods of Groups 27-28, 33, 36, 54, 58, 62, and 65
  - (c) Groups 3-6, 10-14 and the methods of Groups 29-32, 34-35, 37-38, 55-57, 59-61, 63-64, and 66-67,
- and
- (d) Groups 51-53 and the methods of Groups 39-50

as being related as products and processes of use. Citing MPEP § 806.05(h), the Office states that the Groups can be shown to be distinct if either or both of the following can be shown:

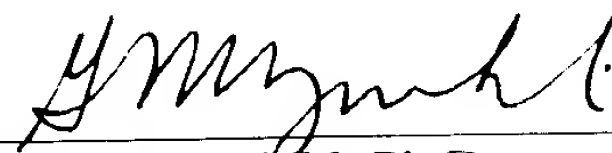
(I) the process for using the product as claimed can be practiced with another materially different product or (II) the product as claimed can be used in a materially different process of using that product. The Office states that each distinct method can be practiced with either of the materially different products as claimed. However, the Office has provided no explanation of how these methods can be practiced with either of the different products, or even why these products are materially different. No examples or reasons have been provided. The Office has simply stated a conclusion of material distinctness, without support.

The Office has characterized the relationship between PRO-C-MG.2, PRO-C-MG.12, PRO-C-MG.45, PRO-C-MG.64 and PRO-C-MG.72 polynucleotides as each being an independent group, not a species. The Office has also characterized the relationship between PRO-C-MG.2, PRO-C-MG.12, PRO-C-MG.45, PRO-C-MG.64 and PRO-C-MG.72 polypeptides as each being an independent group, not a species. No section of the MPEP has been cited for the standard for determining patentable distinctness between these groups. The Office has not provided an explanation or an example to support the determination that the PRO-C-MG.2, PRO-C-MG.12, PRO-C-MG.45, PRO-C-MG.64 and PRO-C-MG.72 polynucleotides are materially different from each other, nor has the Office provided an explanation or an example to support the determination that the PRO-C-MG.2, PRO-C-MG.12, PRO-C-MG.45, PRO-C-MG.64 and PRO-C-MG.72 polypeptides are materially distinct. The Office has simply stated a conclusion of material distinctness, without support.

Applicants submit that the Office has not met the necessary burden in order to sustain the Restriction Requirement. Withdrawal is therefore respectfully requested.

Upon the allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141.

Respectfully submitted,



\_\_\_\_\_  
Gregory M. Zinkl, Ph.D.  
Registration No. 48,492  
Agent for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4200